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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/222,460 | 12/29/1998 | MARC R. HAMMERMAN | A-64236-3-RF | 3124 |

7590 01/14/2003

FLEHR HOHBACH TEST ALBRITTON & HERBERT
SUITE 3400
FOUR EMBARCADERO CENTER
SAN FRANCISCO, CA 941114187

EXAMINER

GUPTA, ANISH

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1654

24

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|-----------------|----------|------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/222,460 | | HAMMERMAN ET AL. | |
| | Examiner | Art Unit | | |
| | Anish Gupta | 1654 | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,7-9,17,20 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,7-9,17,20 and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 10-23-02 is acknowledged. The amendment added claim 25. Claims 1, 4-5, 7-9, 17, 20, 22-24 are pending in this Application.
2. The request filed on 10-23-02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/22,460 is acceptable and a CPA has been established. An action on the CPA follows.
3. All rejections made in the previous office action are hereby withdrawn in view of Applicants arguments. New grounds for rejections follow below.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 4-5, 7-9, 17, 20, and 22-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5,976,524 in view of Liu et al.

The claims are drawn to the treatment of metanephric tissue using a growth factor containing composition for metanephric development.

The US Patent teach a method of increasing nephron mass of a mammalian recipient comprising implanting at least one whole metanephros of an embryonic mammalian donor next to the recipients omentum (see claims). The claims of the Patent state that the metanephros is either allogeneic or a xenogeneic to the recipient. The difference between the prior art and the specification is that the reference does not teach the administration of a growth factor in vitro or in-vivo for metanephric development.

However, Lui et al. teaches that mouse metanephroi, when exposed to IGF-I (100ng/mL) in an organ culture for seven day, resulted in the enlargement of the metanephroi. The reference concludes that IGF-I has a trophic effect on the embryonic kidney during the postinductive period of metanephric development (see abstract). Therefore it would have been obvious s to administer exogenous IGF-I after the transplantation to induce growth and differentiation of the metanephroi tissue prior to transplanting the metanephros tissue.

6. Claims 1, 4-5, 7-9, 17, 20, and 22-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5,976,524 in view of Rogers et al.

The claims are drawn to the treatment of metanephric tissue using a growth factor containing composition for metanephric development.


The US Patent has been discussed supra. The difference between the prior art and the specification is that the reference does not teach the administration of a growth factor in vitro or in-vivo for metanephric development.

The reference of Rodgers et al. teach that TGF- α , when administered to the removed metanephroi, was effective in increasing the size of morphological complex of metanephroi. The reference concludes that the peptide is necessary for growth and development of metanephroi in vitro (see abstract). Therefore it would have been obvious to administer exogenous IGF-I after the transplantation to induce growth and differentiation of the metanephroi tissue since it Rodgers teaches that the TGF- α induced growth of metanephroi tissue.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.




BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600